UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

LIFESCAN, INC. and LIFESCAN SCOTLAND, LTD., Plaintiffs, v. SHASTA TECHNOLOGIES, LLC, INSTACARE CORP., PHARMATECH SOLUTIONS, INC., and CONDUCTIVE TECHNOLOGIES, INC., Defendants.	Case No.: 5:11-CV-04494-EJD **ORDER GRANTING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION; DENYING DEFENDANTS' MOTION TO DISMISS** **[Re: Docket Nos. 174, 176]**

This action arises out of Defendants Shasta Technologies, LLC ("Shasta"), Instacare Corp. ("Instacare"), Pharmatech Solutions, Inc. ("Pharmatech"), and Conductive Technologies, Inc.'s ("Conductive") (collectively, "Defendants") development and sale of GenStrips: blood glucose test strips intended for use in Plaintiffs' LifeScan, Inc. and LifeScan Scotland, Ltd.'s (collectively, "Plaintiffs") OneTouch Ultra test meter. Plaintiffs allege that Defendants' test strips infringe their U.S. Patent Nos. 6,241,862 ("the '862 patent") and 5,708,247 ("the '247 patent") and that Defendants indirectly infringe Plaintiffs' U.S. Patent No. 7,250,105 ("the '105 patent"). The court previously stayed this action as to the '862 and '247 patents. Dkt. No. 245.

Presently before the court is Plaintiffs' Motion for Preliminary Injunction (Dkt. No. 176) and Defendants' Motion to Dismiss as to Count 3 of the First Amended Complaint (Dkt. No. 174). The court held a hearing on Plaintiffs' Motion for Preliminary Injunction on February 21, 2013 and took Defendants' Motion to Dismiss under submission. Having reviewed the parties' briefing and

heard the parties' arguments, the court GRANTS Plaintiffs' Motion for Preliminary Injunction and DENIES Defendants' Motion to Dismiss for the reasons set forth below.

1. TECHNOLOGY BACKGROUND

The parties are competitors in the blood glucose monitoring systems industry. Since 2000, Plaintiffs have marketed and sold the OneTouch Ultra System, a glucose monitoring system used by patients with diabetes. See Pl. Mtn. for Prelim. Inj. 3-4, Dkt. No. 176; Def. Opp. 2; Dkt. No. 203. Plaintiffs are the market leader in glucose monitoring systems, and generate approximately $1 billion in sales annually. Dkt. No. 203 at 2. The system is composed of both a meter and disposable test strips. Dkt. No. 176 at 3. To use the system, a patient places a disposable test strip in the meter, draws a small drop of blood using a lancet, and places the blood on the test strip. Dkt. No. 176 at 3-4. The meter then determines the glucose level in the blood by measuring the electrical current produced when an electrochemical reaction is triggered in the strip by the glucose. Id. at 4.

Plaintiffs' competitive advantage appears to be in its DoubleSure Technology, which is the subject of the '105 patent. Id. DoubleSure Technology is a method designed to improve the reliability and accuracy of glucose measurements. Id. It uses a self-testing strip design, using multiple sensors in a downstream configuration. Id. at 6. Figure 2 depicts the test strip design:

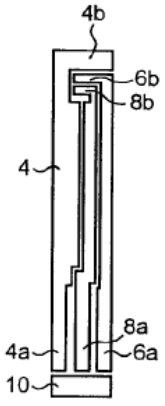

FIG. 2

A drop of blood applied to the top of the test strip flows downstream by capillary action. Id. The test strip has two working sensors (6b and 8b), with one sensor downstream from the

other. Id. This design ensures that the first sensor is completely covered in blood before the second sensor is reached, allowing for more accurate results. Id. The currents are measured at each sensor, and if the values are within a pre-determined range of one another, the reading is accurate. Id. If the difference in values is outside of the acceptable range, the reading may not be accurate and the test strip can be discarded. Id. at 6-7.

Defendants' GenStrips are nearly identical to Plaintiffs' test strips, and are designed specifically to work with the OneTouch Ultra meter. See id. at 5. GenStrips received FDA approval in January of this year, but are not approved for use in any device other than the OneTouch Ultra meter. Id. While GenStrips have not been on the market for the majority of this litigation, Defendants confirmed at the preliminary injunction hearing that their product is now available for purchase. Prelim. Inj. Hr'g Tr. (Rough) 80:20-21 (Feb. 21, 2013).

2. PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

2.1 Legal Standard

Because this motion for preliminary injunction arises in the context of a patent infringement action, the court will apply Federal Circuit law. See Hybritech Inc. v. Abbott Labs., 849 F.2d 1446, 1450, n. 12 (Fed. Cir. 1988). The Federal Circuit requires the court to consider four factors of "universal applicability" in determining whether a grant of a preliminary injunction is appropriate: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the balance of hardships tips in the plaintiff's favor; and (4) the injunction is in the public interest. Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (citing Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7 (2008)). Each of these four factors must be weighed and assessed against the others and against the form and magnitude of the relief requested. Hybritech, 849 F.2d at 1451.

2.2 Likelihood of Success on the Merits

In a patent infringement case, "reasonable likelihood of success on the merits" means that a patentee must show (1) it will likely prove infringement; and (2) its infringement claim will likely withstand challenges to the patent's validity and enforceability. Purdue Pharma L.P. v. Boehringer

Ingelheim Gmbh, 237 F.3d 1359, 1363 (Fed. Cir. 2001). Even at this stage, the court must consider the evidence in light of the presumptions and burdens that will apply at trial. Titan Tire, 566 F.3d at 1376.

A patent is presumed valid at trial. 35 U.S.C. § 282. Thus, the alleged infringer bears the burden of proving an affirmative defense of invalidity by clear and convincing evidence. Titan Tire, 566 F.3d at 1376. If the accused infringer successfully meets its burden, the plaintiff then must come forward with contrary evidence sufficient to overcome the accused infringer's showing. Id. At the preliminary injunction stage, a patent is also presumed to be valid. Similarly, the accused infringer bears the burden to present evidence of invalidity. However, unlike at trial, the accused infringer need only raise a "substantial question" regarding validity. Sciele Pharma Inc. v. Lupin Ltd., 684 F.3d 1253, 1263 (Fed. Cir. 2012); Abbot Labs. v. Sandoz, Inc., 544 F.3d 1341, 1364 (Fed. Cir. 2008); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1359 (Fed. Cir. 2001) (finding that the defendants' burden to raise a "substantial question" did not equate to the "clear and convincing" standard required at trial, but instead could be met by showing "vulnerability"). Notwithstanding the accused infringer's duty to bring forward evidence of invalidity, the ultimate burden remains on the plaintiff to show that the alleged infringer's defense "lacks substantial merit," and that plaintiff is likely to succeed at trial despite the validity challenge. Titan Tire, 566 F.3d at 1377 (quoting New England Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883 (Fed. Cir. 1992)). In determining the likelihood of success on the validity issue, the court must "weigh the evidence both for and against validity that is available at this preliminary injunction stage…[t]hen…if the [court] concludes there is a 'substantial question' concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue." Id.

2.2.1 Patent Exhaustion

Before reaching the issues of infringement and invalidity, the court must first consider whether Plaintiffs are likely to show that the '105 patent has not been exhausted. "The declared purpose of the patent law is to promote the progress of science and the useful arts by granting to the inventor a limited monopoly, the exercise of which will enable him to secure the financial rewards for his invention." Univis Lens Co. v. United States, 316 U.S. 241, 250 (1942) (citing U.S. Const. Art. I, § 8, cl. 8). To strike the proper balance between the public's interest in innovation and an inventor's need for remuneration, the law extends to patentees a monopoly for a limited period of time, during which the patentee maintains the exclusive "right to make, use, and sell" the invention. See Bauer & Cie v. O'Donnell, 229 U.S. 1, 10 (1913). However, that monopoly is not unlimited. Once a patentee sells the patented invention in whole or, under certain circumstances, in part, the monopoly is exhausted. Univis, 316 U.S. at 249. This principle of patent exhaustion is also called the first sale doctrine. See Static Control Components, Inc. v. Lexmark Int'l Inc., 615 F.Supp.2d 575, 578 (E.D. Ky. 2009).

As the Supreme Court recently articulated, the first sale doctrine provides that "the initial authorized sale of a patented item terminates all patent rights to that item." Quanta Comp., Inc. v. LG Electronics, Inc., 553 U.S. 617, 625 (2008). In operation, the doctrine "prohibits patent holders from selling a patented article and then 'invoking patent law to control postsale use of the article.'" Excelstor Tech., Inc. v. Papst Licensing GmbH & Co. KG, 541 F.3d 1373, 1376 (Fed. Cir. 2008) (citing Quanta, 553 U.S. at 638). Because application of the doctrine extinguishes a patentee's monopoly right over the patented item, "[e]xhaustion is triggered only by a sale authorized by the patent holder." Quanta, 553 U.S. at 636.

The parties dispute whether an "authorized sale" has occurred such that the '105 patent could be deemed exhausted. Plaintiffs first distribute their OneTouch Ultra products either by (1) having doctors distribute a free OneTouch Ultra kit, comprised of a meter and 10 test strips, to diabetic patients, or (2) selling the OneTouch Ultra meter alone at a reduced price. Defendants contend that under either distribution scheme, Plaintiffs have transferred ownership of their

patented invention, thus extinguishing their right to control consumers' use of the product. Plaintiffs, however, contend that because they have not received their "reward" for the free kits and because the meter alone does not "substantially embody" the inventive aspects of the '105 patent, exhaustion cannot apply.

2.2.1.1 Free Distribution of OneTouch Ultra Kits

First, the court must consider whether distributing a patented article for free constitutes an "authorized sale." Plaintiffs argue that their free distribution scheme cannot trigger the first sale doctrine because they have not received their "reward" for the patented article. Defendant contends that a free distribution triggers the first sale doctrine because it is the transfer of ownership, not the adequacy of Plaintiff's remuneration, which creates an "authorized sale."

The question presented by the parties—whether it is the transfer of title and ownership or rather the purchase and sale of a patented article that triggers the first sale doctrine—has not been directly addressed by courts of higher authority. In most cases, courts need not consider this distinction because the transfer of ownership is typically accomplished through a traditional sale or licensing agreement. However, in a case such as this where the patented article primarily enters the stream of commerce through a free distribution system, the distinction is a crucial one that must be examined.

In 1859, the Supreme Court considered the question of whether patent exhaustion applied during an extended patent term. Chaffee v. The Boston Belting Co., 63 U.S. 217 (1859). In doing so, the Court reiterated the principles of patent exhaustion, holding that

> [w]hen the patented machine rightfully passes to the hands of the purchaser from the patentee, or from any other person by him authorized to convey it, the machine is no longer within the limits of the monopoly…By a valid sale and purchase, the patented machine becomes the private individual property of the purchaser, and is no longer protected by the laws of the United States, but by the laws of the State in which it is situated.
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> Id. at 223.

However, the court went on to declare that

> it is obvious[] that if a person legally acquires a title to that which is the subject of letters patent, he may continue to use it…as he pleases, in the same manner as if dealing with property of any other kind."
>
> Id.

Because the record did not reflect that the defendants had legally licensed the machine at issue, the Court found them to be "naked infringers" who could not be saved by the principles of patent exhaustion. Id. at 224.

The language used by the Chafee Court in describing the point at which "the machine is no longer within the limits of the monopoly" would seem to support either party's argument in the present case. On the one hand, the Court looked to a "valid sale and purchase" to trigger exhaustion, whereas on the other, the Court pointed to a person's "legally acquir[ing] a title" as the exhaustive moment. A close reading of the opinion would seem to suggest that the way in which a person would "legally acquire[] title" would be through a "valid sale and purchase;" however, the Court did not so explicitly state the principle, leaving the door open for arguments such as Defendants' here.

As the Supreme Court's exhaustion jurisprudence evolved, the Court did not directly address the difference between a "valid sale and purchase" and "legally acquir[ing] a title;" however, the distinctions it has drawn in other areas prove useful to the analysis. In Univis, the Court considered the question of whether the first sale doctrine applied when the patentee, a lens company, sold its patented lens blanks to a wholesaler, who then was required to grind the blanks down to finish them using a standard process cited in the patentee's method patents. 316 U.S. 241 (1942). Because the lens blanks themselves "embodie[d] essential features of [the] patented invention" the court determined that their sale also embodied the "reward" to which the patentee was entitled. 316 U.S. at 251. The Court explained that "the purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward for the use of his invention by the sale of the article" and that beyond that sale, the patentee had no further right to control use of the article. Id.

On its face, the Univis opinion suggests that it is a traditional sale of a patented invention that triggers exhaustion. However, the same day the Court issued its Univis decision, it also issued an order in United States v. Masonite Corp., which steered the exhaustion inquiry away from a focus on traditional sales. 316 U.S. 265 (1942). According to the Masonite Court, the form of the sale of the patented article has no impact on the application of exhaustion; rather, the test simply is "whether or not there has been such a disposition of the article that it may fairly be said that the patentee has received his reward for the use of the article." 316 U.S. at 278 (finding exhaustion where patentee "disposed" of the patented product to a del credere agent with which patentee had "no intimate relationship" and with whom patentee competed, because the arrangement, without more, enlarged the patentee's privilege to fix prices in violation of the Sherman Act). The inquiry thus shifted from whether a "valid sale and purchase" had occurred to whether the patentee had received his "reward" in any form. After Univis and Masonite, the Court did not develop the "reward" inquiry further. Nor did it address any major patent exhaustion issue until 2008, when it issued its opinion in Quanta. In that case, which will be discussed in detail in the following section, the Court acknowledged that an "authorized sale" was required to trigger the first sale doctrine, but did not address the issue of reward in any substantial detail.

In the years since Univis, the Federal Circuit has shed some light on what forms of "reward" trigger exhaustion. In 1993, the court considered the question of whether a licensed seller of a patented product must own the patent rights to that product in order for there to be a sale sufficient to trigger exhaustion. Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1556, 1569-70 (Fed. Cir. 1993). In holding that the patentee-assignee's rights terminated with the sale of the patented product by a licensee acting within the scope of its license, the court noted that

> [w]hile Intel may not in retrospect be pleased with the deal that it made permitting HP to make unrestricted sales, it nevertheless granted HP that right in 1983, presumably for consideration it believed to be of value at that time. It cannot now renege on that grant to avoid its consequences.
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> Id. at 1569.

Later, in TransCore, LP v. Electronic Transaction Consultants Corp., the court found that a settlement agreement containing a broad covenant not to sue for future infringement constituted an "authorized sale" for purposes of patent exhaustion under Quanta. 563 F.3d 1271, 1276-77 (Fed. Cir. 2009). In that case, the plaintiff had received $4.5 million from a competitor in exchange for an unconditional covenant not to sue and a release of all existing claims. When the plaintiff later sued a customer of the competitor for infringement, the Federal Circuit upheld the district court's finding that the plaintiff's patents had been exhausted by the settlement agreement.

More recently, the court has examined the issue in the context of patented seeds. In Monsanto Co. v. Bowman, the court found that patent exhaustion may apply to the original seeds sold, but not to any subsequent generation of those seeds after they have been planted. 657 F.3d 1341, 1347-48 (Fed. Cir. 2011), cert granted 133 S. Ct. 420 (Oct. 5, 2012). In so finding, the court explained that the subsequent generation of seeds constitutes a "newly infringing article" for which the patentee had not received a reward. Id.

The common theme running through this line of cases is consideration. In each case where exhaustion has been found, the transfer of ownership of the patented article was accomplished by some bargained-for exchange: a traditional sale, as in Univis; a licensing agreement, as in Intel; the disposition of an article with a competitor in exchange for higher sale prices, as in Masonite; or a covenant not to sue in exchange for a cash settlement, as in TransCore. In contrast, exhaustion has not been found when the patentee has not received any consideration in exchange for the patented article, as with the second generation seeds in Monsanto.

In this case, when Plaintiffs distribute their OneTouch Ultra kits for free, they receive no remuneration at the moment they part with their patented invention. Rather, Plaintiffs distribute the kits in consideration of patients' anticipated future repeat purchases of Plaintiffs' disposable test strips. Thus, at the moment of disposition, Plaintiffs have not received their reward for their invention. At the hearing, Defendants argued that Plaintiffs receive their reward for the '105 invention within two months of the free distribution of the meters. Hr'g Tr. (Rough) 88:21-24. Such argument belies any suggestion by Defendants that Plaintiffs receive their reward when they

distributes the kits for free—i.e., the parties essentially agree that the "reward" comes in Plaintiffs' repeated sale of disposable test strips to diabetic patients. Because the Supreme Court and the Federal Circuit have emphasized that a patentee's receiving of some reward for his or her invention triggers exhaustion, and because Plaintiffs here do not receive any reward at the time of distribution, Plaintiffs can likely show that patent exhaustion is not triggered by the free distribution of its OneTouch Ultra kits.

2.2.1.2 Plaintiffs' Sale of Meters Alone at a Reduced Price

Having determined that the free distribution of OneTouch Ultra kits likely does not trigger patent exhaustion, the court must now consider whether the sale of the OneTouch Ultra meter alone at a reduced price is sufficient to exhaust the '105 patent. The '105 patent is a method patent that requires both a meter and a test strip for an individual to practice it. As such, the sale of the meter by itself does not necessarily convey the entire invention of the '105 patent to the purchaser, casting the applicability of exhaustion into doubt.

The Supreme Court recently addressed the application of patent exhaustion to method patents in Quanta. In that case, LGE licensed its computer technology patents to Intel, authorizing Intel to manufacture and sell microprocessors and chipsets under the patents. In a separate agreement, LGE required Intel to provide its customers with a written notice that the license between LGE and Intel did not extend to any product made by combining an Intel product with a non-Intel product. Quanta purchased microprocessors and chipsets from Intel and placed them in computers manufactured with non-Intel parts. LGE sued Quanta, asserting that the combination infringed its patents. See Quanta, 553 U.S. at 623-24.

The district court found, and the Federal Circuit affirmed, that patent exhaustion did not apply to method patents and thus that LGE could assert its patent rights against Quanta. See LG Elec., Inc. v. Bizcom Elec., Inc., 453 F.3d 1364, 1370 (Fed. Cir. 2006). The Supreme Court reversed, holding that patent exhaustion does in fact apply to method patents, including the patents at issue in the case. 553 U.S. at 628, 638. In so holding, the Court made clear that when a component of a patented system is sold but is required to be combined with additional components

after the sale in order to fully practice the patented method, the sale of the component only triggers patent exhaustion when the component "substantially embod[ies]" the patents-in-suit. 553 U.S. at 621, 633. According to the Quanta Court, an item "substantially embodies" the patent when it covers the "essential, or inventive, feature" of the patent and when the item's only reasonable and intended use is to practice the patent. Id. at 632-33.

In Quanta, LGE's patents were found to be exhausted because "[e]verything inventive about each patent [was] embodied in the Intel Products" and "the only step necessary to practice the patent [was] the application of common processes or the addition of standard parts." 553 U.S. at 633. In making this determination, the Court relied on its prior reasoning in Univis, which found exhaustion in part because the item sold "embodie[d] essential features of [the] patented invention" whereas the finishing process required to practice the patent was a standard process barely mentioned in the patents-in-suit and thus only "incidental to the invention." 553 U.S. at 632-33 (quoting Univis, 316 U.S. at 250-51). Similarly here, to determine whether the '105 patent has been exhausted by the sale of Plaintiffs' OneTouch Ultra Meter alone, the court must determine whether that meter embodies the "inventive" feature of the '105 patent, and whether the OneTouch Ultra test strips constitute anything more than "standard parts."

The '105 patent specification describes what the inventor perceived as a problem in the art relating to the accuracy of blood glucose measuring devices: inaccurate readings caused by insufficient blood coverage of the working sensor part or by manufacturing defects. '105 patent 1:39-41; 55-58. By teaching two identical working sensor parts configured in such a way to ensure that the first sensor is completely covered in blood before the second sensor is reached, the '105 patent allows for the measurements from the two sensors to be compared. If the results from the two sensors are too disparate, the '105 patent teaches that an error code should appear alerting the user to discard the test strip and try again. See '105 patent, 2:27-30. In this way, the '105 patent's invention is self-testing for accuracy. This solution addresses the problem the inventor identified in the art while still keeping the cost of the disposable test strip low. Id. at 1:21-22, 32-38.

The specification and claims make clear that at the very least both a measuring device and two working sensor parts are required to practice the invention. Particularly, Claim 1 calls for:

> a measuring device said device comprising:
>
> a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;
>
> a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and
>
> a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip
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> ('105 patent 6:55-711)

i.e., the two working sensor parts, as well as:

> applying the sample liquid to said measuring device;
>
> measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;
>
> comparing the electric current from each of the working sensor parts to establish a difference parameter; and
>
> giving an indication of an error if said difference parameter is greater than a predetermined

threshold.

('105 patent 7:12-8:5)

i.e., a measuring device—here, a meter.

In allowing the '105 patent to issue, the patent examiner highlighted the differences in Plaintiffs' working sensor parts from the sensors present in the prior art. The examiner noted that, unlike the prior art, Plaintiffs' two working sensors were identical in size and composition, allowing the charge carriers from each working sensor to be compared. Supplemental Declaration of Mark Meyerhoff ("Meyerhoff Supp. Decl.") Ex. 18 at 8-9. Thus, the patent examiner considered the sensors to be an important component of the '105 patent's invention.

While "some or all of the sensor parts may be provided as part of an integrated device," the specification sets forth a preferred embodiment in which the working sensor parts are provided in a downstream configuration on a "removable test member," described in Claim 1 as a "disposable test strip." '105 patent 2:57-59; 7:11. Tellingly, the '105 patent itself devotes much of the specification and most of the claim language to describing the sensor parts contained in the disposable test strips and the design of the strips themselves. Figures 1-7 of the '105 patent highlight various elements of the proposed test strip, but no figure relates to the meter or any other measuring device. Similarly, the majority of the specification and claim language is devoted to describing the arrangement, composition, and operation of the working sensor parts. By contrast, the specification and claims devote little space to describing the meter.

As evidenced by the patent examiner's reasoning and the depth of treatment the patent specification and claims afford to the test strips, the strips are likely more than "incidental" to the '105 patent's invention. See Quanta, 553 U.S. at 633. Defendants argue that under Quanta the test strips must amount to a "unique feature of the patented system" in order to avoid exhaustion. Dkt. No. 203 at 10. Plaintiffs press for a narrower reading of Quanta, which would prevent exhaustion from applying if the strips constitute anything more than a "standard component" used to practice the '105 patent. Dkt. No. 176 at 13. The court need not consider these competing interpretations because under either reading of Quanta, the meters alone do not "substantially embody" the '105

patent. As the examiner noted, the particular design and arrangement of the working sensors on Plaintiffs' test strips contribute substantially to the novelty of the '105 patent's method. Accordingly, the strips themselves are more than mere "standard components" and moreover likely constitute a "unique feature of the patented system." Because the strips are significant to the novelty of the '105 invention, the meters alone simply cannot "all but completely practice" or embody the "essential" or "inventive" feature of the '105 patent as required by Quanta. 553 U.S. at 632-33.

Having found that Plaintiffs' OneTouch Ultra meters likely do not embody the inventive feature of the '105 patent, the court need not reach the parties' arguments regarding the reasonable non-infringing uses of the OneTouch Ultra meter. The Quanta court found exhaustion because LGE's chipsets and microprocessors substantially embodied the patents-in-suit, as evidenced by the facts that the products had no reasonable non-infringing uses and embodied the essential features of the patents-in-suit. 553 U.S. at 631-32. However the court does not consider these bases to be completely separate grounds on which to find substantial embodiment and consequently, exhaustion. Plaintiffs' showing that they likely have not sold their invention by selling the OneTouch Meter alone is sufficient to demonstrate a likelihood of success on exhaustion.

2.2.1.3 Implied License, Sherman Act, and Breach of Contract Arguments

Because the court has found that patent exhaustion likely does not apply to the free distribution of Plaintiffs' OneTouch Ultra kits or the sale of Plaintiffs' meters alone, Defendants' Sherman Act and contract arguments are of no moment. Such arguments anticipate Plaintiffs' response should the court find exhaustion, but add nothing to the discussion in the event Plaintiffs prevail on that issue. Plaintiffs' implied license argument is similarly irrelevant because, though such an argument could be pertinent given that the court has found a likelihood of success on exhaustion, Defendants have not raised an implied license defense.

2.2.2 Indirect Infringement

In order to show a likelihood of success on the question of Defendants' inducing and contributory infringement, Plaintiffs must first show a likelihood of success in proving that consumers directly infringe the '105 patent when using Defendants' GenStrips in OneTouch Ultra meters. Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 526 (1972) ("if there is no (direct) infringement of a patent there can be no contributory infringer") (citation omitted); Akamai Tech. Inc. v. Limelight Networks Inc., 692 F.3d 1301, 1308 (Fed. Cir. 2012) ("An important limitation on the scope of induced infringement is that inducement gives rise to liability only if the inducement leads to actual infringement."). To show direct infringement, Plaintiffs must demonstrate that every step of the '105 patent's method is practiced when consumers use GenStrips in the OneTouch Ultra meter. See Meyer Intellectual Prop. Ltd. v. Bodum, Inc., 690 F.3d 1354, 1366 (Fed. Cir. 2012). Because the parties do not dispute the inducing or contributory conduct of Defendant, the court must only determine the likelihood of success on the direct infringement question.

Defendants here do not stake out the typical litigation position of accused infringers vehemently denying infringement on the basis of differences between their product and the patented invention. In fact, the parties all but concede that Defendants' GenStrips are identical at least in configuration and operation to Plaintiffs' strips. By extension, the parties appear to agree that, when used by a consumer in a OneTouch Ultra meter, Defendants' GenStrips would enable that consumer to practice the '105 invention in the same manner as Plaintiffs' test strips. Having no sincere argument as to notable differences between GenStrips and Plaintiffs' strips, Defendants instead urge the court to find that direct infringement is impossible, because neither GenStrips nor Plaintiffs' strips are capable of practicing the '105 patent as drafted.

Defendants hinge this unusual argument on the meaning of "proportional" in Claim 1 of the '105 patent. Particularly, Defendants urge the court to accept that the '105 patent uses science that is "simply incorrect," requiring the electric current itself, rather than the measurement of that

current through the manipulation of the current data, to be proportional to the amount of glucose in the blood. Wang Decl. ¶ 28. If that interpretation is correct, then neither GenStrips nor Plaintiffs' OneTouch strips can satisfy the '105 patent limitations because, when using those devices, what is actually proportional is the manipulated measurement of the current, while the current itself is merely "correlated" to the glucose content in the blood. See Declaration of Dr. Joseph Wang ("Wang Decl") ¶ 26, Dkt. No. 206.

Plaintiffs contend that this argument requires a "strained and unnatural" reading of proportionality as it is understood in the field of electrochemistry. Hr'g Tr. (Rough) 22:6-7. According to Plaintiffs, the art's understanding of proportionality is not that of a mathematical fixed ratio of glucose to current as suggested by Defendants. Instead, proportionality is a calculation that relies on a linear equation adjusted for background current, environmental factors, and temperature. Meyerhoff Supp. Decl. ¶¶ 149-51.

Defendants themselves appear to rely on this understanding of proportionality when convenient. For instance, in their first obviousness argument, Defendants explain to the court that the Winarta '229 patent uses proportionality in the same way as Plaintiffs' '105 patent. Wang Decl. ¶ 35. Thus Defendants are asking this court to view not only Plaintiffs' patent, but also other art references, as employing "incorrect science." Additionally, Defendants appear to rely on the "incorrect" proportionality interpretation in their dealings with the FDA. Defendants' Instructions for Use ("IFU") state in relevant part: "Glucose in blood combines with an enzyme in the test strip. This produces an electric current in the Meter in proportion to the glucose level." Meyerhoff Supp. Decl. Ex. 2. Defendants make much of the inclusion of the chemical reaction in this statement, but their argument is of no moment. Though it is clear that a chemical reaction produces the electric current, Defendants nevertheless have stated to the FDA that that current is "in proportion" to the glucose level in the blood.

Having illustrated the substantial parity between their and Defendants' test strips, Plaintiffs have demonstrated a likelihood of success on the question of infringement. The court is not persuaded that Defendants' reading of proportionality in the '105 patent is enough to generate a

"substantial question" as to infringement. Such an understanding seems contorted and divorced from the art, and even contrary to Defendants' own usage of the term. Accordingly, Plaintiffs are likely to succeed on the ultimate question of infringement.

2.2.3 Invalidity

Defendants assert an affirmative defense of invalidity under 35 U.S.C. §§ 101 and 112 for lack of utility and enablement and under 35 U.S.C. § 103 for obviousness. At this stage in the proceedings, the court must weigh both parties' evidence to determine whether a substantial question exists as to invalidity. Titan Tire, 566 F.3d at 1377. As discussed in the previous section, Plaintiffs have shown a likelihood of success on the question of infringement, including on the question of the interpretation of proportionality in the '105 patent. Because Defendants rely on the same argument to support their §§ 101 and 112 defense as they do to support their assertion of non-infringement, the court finds that Plaintiffs have similarly shown a likelihood of overcoming Defendants' validity challenge on those grounds. The court therefore must only consider whether on balance, the evidence regarding obviousness is such that a substantial question exists as to the '105 patent's validity.

A patent is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The determination of obviousness is "a question of law based on underlying findings of fact." In re Kubin, 561 F.3d 1351, 1355 (Fed. Cir. 2009). The Supreme Court has instructed courts to address the question of obviousness against the "background" of three inquiries: 1) the scope and content of the prior art; 2) differences between the prior art and the claims at issue; and 3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966). Courts must also consider "secondary considerations" that may be relevant to obviousness, such as "commercial success" and "long felt but unsolved needs." Id. Additionally, obviousness can only be found when the prior art discloses all limitations of the

claim or claims. See CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1342 (2003) (citing In re Royka, 490 F.2d 981, 985 (CCPA 1974)).

In this case, Claim 3, which Defendants argue is obvious, depends from Claim 1 of the '105 patent. '105 patent 8:9. Thus in order for Claim 3 to be found obvious, the limitations of both Claim 1 and Claim 3 must be disclosed by the prior art. Defendants have come forward with eighteen separate obviousness grounds, which they contend encompass every element of Claims 1 and 3. Each ground relies on some combination of ten prior art references, and each ground relies on either Winarta '229 or Nankai '420 as a primary reference. The thrust of these arguments is that the '105 patent is obvious because prior art discloses, most importantly, the elements of employing a disposable test strip containing multiple sensors, positioning the sensors in a downstream configuration, taking multiple measurements, comparing the measurements to establish a difference parameter, and presenting an error code if the difference is outside a predetermined range, and because the combination of these elements yields nothing more than a predictable result. See KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007).

2.2.3.1 Defendants' Prior Art References

The individual references and the parties' principal arguments as to each are as follows:

Winarta '229 (U.S. Patent No. 6,258,229)

Winarta '229 purports to solve the problem in the prior art of requiring too much test sample from patients, who generally are required to test their levels several times a day and experience much pain and inconvenience in obtaining the required test sample volume. Winarta '229 patent 3:14-21. When patients produce insufficient sample volume, the resultant readings can be inaccurate. To address this and other concerns, Winarta teaches the use of a reference electrode, a working electrode, and a pseudo-working electrode on a disposable test strip. See id. at 4:12-15. The pseudo-working electrode is positioned downstream from the reference and working electrodes. Once the sample liquid hits the pseudo-working electrode, the current produced "triggers the reading meter to start the measurement and analyte concentration determination process," "obviat[ing] reliability and accuracy problems due to an insufficient sample size." Id. at

5:63-6:1. Winarta '229 was not considered by the examiner, but Plaintiffs contend that the examiner was aware of it because he considered the Winarta '451 patent, which dealt with similar subject matter and was filed the same day as Winarta '229.

Defendants contend that Winarta discloses a test strip that covers every feature of the "disposable test strip" component of the measuring device of Claim 1 of the '105 patent, including multiple sensors and the downstream configuration. Dkt. No. 203 at 23. Because Winarta provides these elements, Defendants suggest that "the test strip of Winarta ('229) is capable of taking multiple measurements." Wang Decl. ¶ 35. Plaintiffs argue that such an interpretation is a stretch because Winarta would require "significant design modifications—which it does not advocate and which are contrary to its teaching—before it would actually be 'capable' of the multiple measurements described by the '105 patent." Pl. Reply Br. 15, Dkt. No. 215. The particular design modifications at issue would involve adjusting the pseudo-working electrode, which per Winarta is smaller than the working sensor and does not measure glucose, into a working sensor of the same size as the first working sensor. Such significant changes, according to Plaintiffs, would preclude a finding that Winarta renders obvious the comparing of glucose measurements at two sensor parts, or providing an error message based on any comparison.

Nankai '420 (U.S. Patent No. 5,120,420)

Nankai '420 also addresses the issue of accuracy in measurement, teaching that higher accuracy can be achieved by "providing a plurality of electrode systems for the same sensor and obtaining a mean value of the response levels." Nankai '420 patent 8:42-46. Nankai's solution teaches multiple working sensor parts, the readings from which can be averaged to increase precision. The examiner considered Nankai '420 in granting the '105 patent.

Defendants argue that Nankai renders Plaintiffs' test strips obvious because it contains every element of the test strip, albeit in a different configuration. Dkt. No. 203. at 27. Plaintiffs argue that Nankai did not identify the problems of insufficient blood fill or manufacturing defects, and that Nankai's solution of arranging multiple working electrodes parallel to each other and averaging the result would not address these problems. Rather than teaching a downstream

configuration, Nankai teaches placing the working electrodes parallel to one another, arranged such that the sample liquid reaches the reference sensor last. Nankai '420 patent Figs. 12, 13. However, Nankai does state that other arrangements are possible. Id. at 8:47-52. Plaintiffs also argue that Nankai teaches nothing more than averaging the results of the multiple measurements to provide a more accurate reading, i.e. that Nankai does not teach comparing results from multiple tests and providing an error indication if the difference between the measurements is out of range. Instead, Nankai's solution would "simply mix good data with bad." Dkt. No. 215 at 17.

Fujiwara '441 (U.S. Patent No. 6,004,441)

Fujiwara '441 teaches measuring the current after a predetermined time in order to allow the glucose to oxidize. Wang Decl. ¶ 96. That patent also teaches multiple sensors, but only deploys one sensor as a working sensor part. The examiner considered the Fujiwara '441 patent in granting the '105 patent, and distinguished it stating "[a]lthough the sensor parts of the biosensor of Fujiwara could be used as working sensor pars [sic] and a reference sensor part as claimed Fujiwara only uses the middle sensor part, electrode 4, as a working sensor part, and the outer sensor parts, electrodes 5, as counter (counter/reference) sensor parts." Meyerhoff Supp. Decl. Ex. 18 at 8. Defendants argue that Fujiwara '441 renders obvious the use of a pause between the application of the sample liquid and the measuring of the current. Plaintiffs contend that Fujiwara's teachings were common knowledge to one of skill in the art, but that Fujiwara would not lead one to construct the strip in the manner taught by the '105 patent.

Yee '256 (U.S. Patent No. 5,672,256)

Yee '256 teaches that the arrangement of electrodes does not affect their characteristics and that multiple measurements should be taken and averaged together to address errors caused by test strip construction. Id. at ¶ 51, 83. Yee also teaches that there is a range of errors that is impermissible, and thus Defendants argue that it would have been obvious to give the user an error indication. Dkt. No. 203 at 25. Plaintiffs contend that the use of an error message was common knowledge to one of skill in the art, but that Yee, like Fujiwara, would not lead one confronted with the problems identified by the '105 patent to construct the strip as it is claimed.

Stewart '891 (U.S. Patent No. 6,540,891)

Stewart '891 discloses that glucose meters used with disposable strips typically have electronic features designed to detect invalid results and report an error condition. Wang Decl. ¶ 87. Defendants use this reference to argue that Plaintiffs' showing of an error message would have been predictable. Plaintiffs acknowledge that this teaching would have been standard to someone of skill in the art, but again argue that Stewart '891 would not lead anyone to construct the design and methods claimed by the '105 patent. Meyerhoff Supp. Decl. ¶ 127.

Say '752, Schulman '344, and Horii '998 (U.S. Patent Nos. 6,175,752; 5,791,344; and 5,004,998)

Say '752, Schulman '344, and Horii '998 all involve a separate but related art of continuous monitoring technology. These patents concern sensors that are implanted in the body for a period of days or weeks, then removed and replaced. See Say '752 patent 27:19-25. To address the problem of when to replace the sensor, the patents teach multiple working electrodes whose output signals can be compared to determine whether the sensor or sensors are working properly. Id. at 2:13-28. Both the Schulman '344 and the Horii '998 patents were considered by the examiner in granting the '105 patent. Defendants lean on these patents to suggest that comparing multiple measurements would have been obvious. Plaintiffs contend that these patents pertain to a non-analgous art that does not face the same problems of inadequate blood fill or manufacturing defects that the '105 patent solves, and that as such one of skill in the art would not have been lead to construct the '105 test strip as taught by the patent.[1]

Khazanie and Lichten

The Khazanie and Lichten textbooks are mathematics textbooks. Defendants rely on these books to argue that one of ordinary skill in the art would have known how to determine a "mean

[1] The court OVERRULES Defendants' Objection to Reply Evidence (Dkt. No. 228). While Defendants are correct in asserting that Plaintiffs had opportunity prior to their Reply brief to define a person of ordinary skill in the art, the court does not rely on the new definition contained in the Supplemental Declaration of Mark E. Meyerhoff. Similarly, the court has not relied on the Supplemental Declaration of Peter Menziuso.

deviation," a "standard deviation," or an "average duration" when averaging numbers. Plaintiffs contend that these sources are "background noise" to a person of skill in the art, but do not pertain to the problem addressed by or the solution contained in the '105 patent. Dkt. No. 215 at 19.

2.2.3.2 Plaintiffs' '714 Patent Application

In addition to the prior art references, Defendants also argue that the court should consider the USPTO's initial rejection of Plaintiffs' '714 patent application on obviousness-type, obviousness, and anticipation grounds and Plaintiffs' subsequent abandonment of the '714 patent application as evidence suggesting that the claims approved in the '105 patent are obvious. The '714 patent application sought to expand the coverage of the '105 patent. Using a transitive argument Defendants suggest that because the patent examiner found the claims of the '714 application to be patentably indistinguishable from the '105 patent claims, and because the examiner also found that the '714 application claims were not patentable based on prior art, that the '105 patent must also be invalid under the prior art. The court is not inclined to accept this argument at this stage in the proceedings. Initial rejections are quite common, and a company's decision to abandon a patent application may be made on any number of bases. Therefore, the court does not find that the USPTO's rejection of the '714 patent application or Plaintiffs' subsequent abandonment of that application generates a substantial question as to the validity of the '105 patent.

2.2.3.3 Obviousness Determination

The court finds that, on the whole, Plaintiffs have shown a likelihood of overcoming Defendants' obviousness challenges. Plaintiffs have rebutted Defendants' obviousness evidence with compelling evidence and argument showing that the patent examiner considered many of the references cited by Defendants, that one of skill in the art would not necessarily have had reason to combine the known elements, that the prior art does not cover each and every limitation of Claim 3, and that Defendants improperly used hindsight.

First, the court notes five of Defendants' references were considered by the patent examiner (Nankai '420, Horii '998, Yee '256, Schulman '344, and Fujiwara '441), and two references (Say

'752 and Stewart '891) are arguably cumulative of these references. Additionally, the examiner considered Winarta '451, which involved related technology and was filed on the same day as Winarta '229. The examiner ultimately issued the '105 patent over those references. See OSRAM Sylvania, Inc. v. Am. Induction Tech., Inc., 701 F.3d 698, 705 (finding that "prior consideration of a reference during prosecution may carry some weight" even when accused infringer does not bear a heightened burden on validity).

Second, Defendants' combinations of references are not compelling because the art was not concerned with the problems Plaintiffs addressed in the '105 patent. While accuracy of measurement was a generally known issue, the Nankai '420 patent purported to solve it using the mean of the sensor measurements. Similarly the issue of insufficient blood fill was touted as solved by the Winarta '229 patent. Thus even assuming that the elements of multiple working sensors of equal size, arranging those sensors in a downstream configuration, taking multiple measurements, and comparing the measurements to determine error were known, the result of the combination of those elements is not predictable. KSR, 550 U.S. at 418. Rather, the combination produced a novel invention solving problems previously unidentified in the art. See Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1377 (Fed. Cir. 2012) ("Often the inventive contribution lies in defining the problem in a new revelatory way.")

Third, no combination of references presented by Defendants covers each and every limitation of Claims 1 and 3. It seems that at best, each combination proposed by Defendants demonstrates that the idea of using multiple sensors to take measurements that could be averaged and deliver an error code was known in the art. But Defendants have not sufficiently demonstrated that the idea of using two working sensors of identical size and composition, or comparing the sensor readings in a way other than averaging them would have been obvious to a person of skill in the art. Winarta '229 describes multiple sensors in a downstream configuration, but only one of those sensors is truly a working sensor, and the sensors vary in size. Say '752 describes comparing readings from a single sensor or from multiple sensors to determine inaccuracies, but does not teach that the sensors be the same size, or even that multiple sensors must be used. Nankai '420

teaches the averaging of readings from multiple sensors, and arguably addresses the need for sensors to be the same size, but again does not address the inaccuracies that can still result from the averaging technique. The mathematics textbooks stand for the general proposition that one of skill in the art would have known the method and use of standard deviations, but do not persuasively suggest any reason one of skill in the art would have used standard deviations to solve the new problems identified by the '105 patent.

Finally, both the combinations themselves and secondary considerations suggest that Defendants have improperly used hindsight to construct these obviousness combinations. See Graham, 383 U.S. at 36. Revealingly, Dr. Wang relies heavily on his presumption that the invention is obvious in view of Winarta '229 because that patent's test strip would have been "capable of taking multiple measurements." However, as Plaintiffs have pointed out, Winarta likely teaches away from the design modifications that would be required to accomplish the taking of multiple measurements. Defendants have not made clear why one of skill in the art would have had reason to modify the Winarta invention and combine its teaching with those of the other references. Instead, such a finding suggests that Defendants' obviousness analysis improperly started with the patented invention and then reached back to the prior art seeking out any reference that touched on the individual elements comprising Plaintiffs' invention. See Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1368-69 (Fed. Cir. 2012) (reversing district court's finding of obviousness in part because significant evidence of teaching away led to the conclusion that "hindsight provides the only discernible reason to combine the prior art references").

Secondary considerations such as the commercial success of the OneTouch Ultra System and Defendants' near-exact copying of Plaintiffs' test strip also suggest that the '105 patent's method would not have been obvious to one having skill in the art. These "objective indicia 'may often be the most probative and cogent evidence of nonobviousness in the record.'" Mintz, 679 F.3d at 1378 (citing Ortho–McNeil Pharm. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed. Cir. 1985) (finding that objective indicia "may be the most pertinent, probative, and revealing evidence

available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue."). Plaintiffs promote the "DoubleSure Technology" of the '105 patent on their OneTouch Ultra products' packaging and in their marketing, and their products have achieved commercial success. Moreover, Plaintiffs have become the market leader. That such success appears to be connected to the patented invention is strong evidence of nonobviousness. See Sciele Pharma, Inc. v. Lupin Ltd., 684 F.3d 1253, 1259 (Fed. Cir. 2012). Additionally, as discussed in Section 2.2.2, Defendants' test strips appear to be nearly identical to Plaintiffs' strips. This copying also constitutes strong evidence of non-obviousness. Windsurfing Int'l Inc. v. AMF, Inc., 782 F.2d 995, 1000 (Fed. Cir. 1986) ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

2.2.4 Determination of Likelihood of Success on the Merits

The court finds that Plaintiffs have demonstrated a likelihood of success on the merits. Plaintiffs have demonstrated a likelihood of overcoming Defendants' patent exhaustion challenge because they do not receive their reward until months after they distribute the OneTouch Ultra system kits for free, and because the meters alone do not substantially embody the '105 patent. Additionally, Plaintiffs have shown that Defendants likely indirectly infringe the '105 patent. Defendants' test strips are nearly identical to Plaintiffs', and consumers likely practice the '105 patent when they use GenStrips in a OneTouch Ultra meter. Defendants have raised numerous obviousness arguments; however, Plaintiffs have come forward with sufficient evidence to suggest that no substantial question exists as to the '105 patent's validity. Therefore, this first factor weighs in favor of an injunction.

2.3 Irreparable Harm

Having found a likelihood of success on the merits, the court must now consider whether Plaintiffs will be irreparably harmed in the absence of an injunction. Until recently, a finding of likelihood of success on the merits entitled the movant to a presumption of irreparable harm. However, in 2011 the Federal Circuit made clear that, in light of eBay v. MercExchange L.L.C., the presumption no longer applies. Robert Bosch LLC v. Pylon Mfg. Corp., 659 F.3d 1142, 1148-

49 (Fed. Cir. 2011) (discussing 547 U.S. 388 (2006)). The court noted that despite its abandoning of the presumption, "it does not follow that courts should entirely ignore the fundamental nature of patents as property rights granting the owner the right to exclude." Id. Particularly relevant here, the court indicated that irreparable harm is more easily found when the parties are direct competitors in the same market. See, e.g. id. at 1153-54.

Plaintiffs assert that the introduction of Defendants' GenStrips to the market poses an "existential challenge" to the viability of Plaintiffs' business, and moreover, that Defendants will not have the resources to pay any damages award ultimately incurred. Dkt. No. 176 at 16. Defendants intend to sell their GenStrips at one-half the price of Plaintiffs' strips, and Defendants have projected $173.5 million in U.S. sales in the first full year. Declaration of Peter Menziuso ("Menziuso Decl.") ¶¶ 21, 22, Exs. R, S, U, Dkt. No. 176-3. Given Defendants' pricing structure, this projected sales figure does not accurately reflect the potential losses to Plaintiffs, which would be far greater. Menziuso Decl. ¶ 24. Defendants' pricing structure would also cause price erosion because Plaintiffs would likely need to cut the prices of their strips in order to compete, making it extremely difficult to raise prices back to the earlier level if and when GenStrips are removed from the market. Id. at ¶ 36.[2] Plaintiffs further contend that the sale of Defendants' GenStrips threatens less concrete forms of harm. Particularly, the sale of GenStrips stands to jeopardize Plaintiffs' market share and its position as market leader (See Menziuso Decl. ¶ 7), poses a threat to Plaintiffs' goodwill and reputation (Menziuso Decl. ¶¶ 28, 33, 36-39), and could lead to a reduction in Plaintiffs' research and development budget (Menziuso Decl. ¶ 46).

Defendants do not seriously dispute any of the factual evidence submitted by Plaintiffs. Rather, they contend that Plaintiffs cannot establish irreparable harm because they have not proven a causal nexus between the infringement of the '105 patent and the harm Plaintiffs allegedly will suffer. Relying on the Federal Circuit's decision in Apple, Inc. v. Samsung Electronics Co., which

[2] In their Response to Supplemental Declarations Filed by Plaintiff In Support of Plaintiffs' Motion for a Preliminary Injunction (Dkt. No. 234), Defendants argue that the American Taxpayer Relief Act ("ATRA") has rendered Plaintiffs' price erosion argument irrelevant. This brief does not change the court's analysis of irreparable harm as Plaintiff has demonstrated multiple forms of harm aside from price erosion.

held that irreparable harm is not proven "if consumers buy that product for reasons other than the patented feature," Defendants argue that it is Plaintiffs' distribution scheme, and not their technology, which drives demand. 695 F.3d 1314, 1374 ("Apple II"). The court is not persuaded by this argument. Unlike a smartphone, which contains a myriad of features, test strips designed for use in the OneTouch Ultra meter embody a substantial part of the patented feature and not much else. That Plaintiffs have become the market leader suggests that they possess a superior technology, the technology of the '105 patent.

Defendants further contend that even if a nexus between the infringement and the harm could be established, that Plaintiffs' lost sales and market share do not constitute irreparable harm. Defendants point to Abbott Laboratories v. Andrx Pharmaceuticals, Inc. for the proposition that lost sales alone are insufficient to demonstrate irreparable harm. 452 F.3d 1331, 1348 (Fed. Cir. 2006). However, Defendants' reliance on that case is inapposite. In Abbot Labs., the patentee had failed to establish likelihood of success on the merits, was unable to quantify its lost sales or hardship, and did not "clearly establish[] that monetary damages could not suffice." Id.

The surrounding circumstances are quite different here. First, Plaintiffs do not rely on lost sales alone; Plaintiffs have pointed to multiple forms of harm they will likely experience in the absence of an injunction. Second, as discussed in the previous section, Plaintiffs have demonstrated a likelihood of success on the merits. Third, Plaintiffs have presented concrete evidence regarding their potential losses based on Defendants' own projections. Plaintiffs' argument is particularly compelling in this case because, given that the FDA has only approved GenStrips for use in Plaintiffs' OneTouch Ultra meter, the parties are faced with a zero-sum game in which every sale made by Defendants is likely a sale lost by Plaintiffs. Finally, Plaintiffs have sufficiently shown a likelihood of Defendants' inability to pay a damages award at the end of trial. Plaintiffs have presented evidence suggesting that Defendants have no income stream from anything other than the sale of GenStrips, and have minimal cash on hand. See Dkt. No. 137 at 11 (in which counsel for Shasta admits that Shasta has "no product and no income stream

whatsoever"); Menziuso Decl., Ex. V at F-6 (reflecting Instacare's[3] net loss of more than $2 million for fiscal year 2011); Menziuso Decl., Ex. W at 5 (confirming Instacare's net loss for the nine months ending September 30, 2012 and reflecting net cash of only $7590). While Defendants' income streams certainly stand to strengthen dramatically now that GenStrips have entered the market, the court agrees with Plaintiffs that it is unlikely Defendants will have the ability to pay the full amount of monetary damages that could be awarded at trial. Defendants' pricing structure necessarily implies that Defendants' revenues will never equate to Plaintiffs' losses. Thus without revenues from other sources, it will be impossible for Defendants to satisfy a judgment covering the entirety of Plaintiffs' damages. The court therefore finds that Plaintiffs have made a clear showing that they may be irreparably harmed in the absence of an injunction.

2.4 Balance of Hardships

Next the court must determine whether Plaintiffs have demonstrated that the balance of hardships tips in their favor. Defendants rely on the relative David and Goliath stature of the parties to show that their hardship outstrips any hardship experienced by Plaintiffs. While "[t]he hardship on a preliminarily enjoined manufacturer who must withdraw its product from the market before trial can be devastating," the hardships may nonetheless weigh in favor of the patentee in circumstances such as these. Ill. Tool Works, Inc. v. Grip–Pak, Inc., 906 F.2d 679, 683 (Fed. Cir. 1990). The balance tips towards the patentee because "one who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against a continuing infringement destroys the business so elected." Bosch, 659 F.3d at 1156 (quoting Windsurfing Int'l Inc. v. AMF, Inc., 782 F.2d 995, 1002 n. 12 (Fed. Cir. 1986)). The court recognizes that Defendants are small companies who may not be able to bear the brunt of a preliminary injunction. However, this lawsuit was filed more than eighteen months ago, on September 9, 2011, and Defendants only received FDA approval and commenced sales of GenStrips, to the best of the court's knowledge, in January 2013. It would thus appear that Defendants have taken a "calculated

[3] The court is aware that Instacare has changed its name to Decision Diagnostics Corp. ("DDC"), and that Exhibits V and W reflect DDC's financial data; however, as the parties have not filed any notice or stipulation regarding this name change, the court will continue to refer to this entity as Instacare.

risk" by launching GenStrips during the pendency of this litigation. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1382 (Fed. Cir. 2006). Should the court deny a preliminary injunction, it would in essence require Plaintiffs to "compete against their own patented invention" to their detriment. Bosch, 659 F.3d at 1156. Under these circumstances, where Plaintiffs have demonstrated a likelihood of success on the merits, such an outcome would be improper. Accordingly, this factor favors the entry of a preliminary injunction.

2.5 Public Interest

Finally, the court must consider whether an injunction weighs in the public interest. Defendants argue that the public interest must caution against an injunction, because removing GenStrips from the market would deny the public a low-cost alternative to Plaintiffs' product. Plaintiffs rely on the purposes of the patent laws to support an injunction. While Defendants' argument is certainly reasonable, the court agrees with Plaintiffs.

The "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985). The Federal Circuit has specifically recognized the importance of protecting patent rights in the medical field because the system "provides incentive to the innovative drug companies to continue costly development efforts." Sanofi-Synthelabo, 470 F.3d at 1383. Where, as here, the court has found that the patentee has demonstrated a likelihood of success on the question of infringement, "there can be no serious argument that public interest is not best served by enforcing [the patent]." Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008). Thus, the court finds that the public interest weights slightly in favor of granting an injunction in this case.

2.6 Conclusion

For the foregoing reasons, the court GRANTS Plaintiffs' Motion for Preliminary Injunction. Defendants, along with their officers, directors, partners, agents, servants, employees, attorneys, subsidiaries, and those acting in concert with any of them are enjoined from making, using, offering to sell, or selling within the United States, or importing into the United States,

GenStrips. As a condition of the preliminary injunction and pursuant to Federal Rule of Civil Procedure 65(c), the court will require Plaintiffs to post security in an amount sufficient to secure payment of any damages sustained by Defendants if they are later found to have been wrongfully enjoined. Therefore, Defendants shall submit evidence concerning the proper amount of bond within five days of the date of this order. Plaintiffs shall submit response evidence concerning the proper amount of bond five days thereafter. Neither party's brief shall exceed ten pages in length. The court will not consider any further responses from the parties. This Order shall be held in abeyance until Plaintiffs' posting of the bond in the amount determined by the court.

The parties are further ORDERED to meet and confer and submit a joint status report within thirty days from the date of this Order. In the status report, the parties shall address (1) their intentions regarding any appeal of this Order; (2) if appealed, whether the parties intend to seek a stay of proceedings pending the appeal, and (3) the parties' positions regarding alternative dispute resolution.

3. DEFENDANTS' MOTION TO DISMISS

Defendants seek to dismiss Count Three of Plaintiffs' First Amended Complaint—Declaratory Judgment for Indirect Infringement of the '105 Patent—on the same exhaustion and Sherman Act grounds they have presented to contest Plaintiffs' Motion for Preliminary Injunction. As discussed in Section 2.2.1, Plaintiffs have not only stated a claim on this count, but have demonstrated a likelihood of success on it. Accordingly, for the reasons set forth in Section 2.2.1, Defendants' Motion to Dismiss is DENIED.

IT IS SO ORDERED

Dated: March 19, 2013

EDWARD J. DAVILA
United States District Judge